

Kenny McCleary  
Eli Lilly and Company - Tippecanoe Laboratories  
P. O. Box 685  
Lafayette, IN 47902

Re: Minor Source Modification No:  
157-12124-00006

Dear Kenny McCleary:

Eli Lilly and Company - Tippecanoe Laboratories applied for a Part 70 operating permit on October 10, 1996 for a pharmaceutical manufacturing plant. An application to modify the source was received on . Pursuant to 326 IAC 2-7-10.5(d)(4)(B)(i) the following emission unit is approved for construction(replacement of like kind tank) at the source:

One (1) 500 gallon general process tank, designated as T31A still tank 693, with a maximum capacity of sixty (60) gallons of solvent per minute, and controlled by the existing RTOs or condenser for VOC emissions, and an existing scrubber for SO<sub>2</sub> emissions, and exhausting to two(2) stacks, identified as RTO1 and/or RTO2. CO and NOx emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.

The proposed Minor Source Modification approval will be incorporated into the pending Part 70 permit application pursuant to 326 IAC 2-7-10.5(l)(3). The source may begin operation upon issuance of the source modification approval.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter call (800) 451-6027, press 0 and ask for Shantanu Pahi or extension 3-0868, or dial (317) 233-0868.

Sincerely,

Paul Dubenetzky, Chief  
Permits Branch  
Office of Air Management

Attachments

spahi

cc: File - Tippecanoe County  
U.S. EPA, Region V  
Tippecanoe County Health Department  
Air Compliance Section Inspector - Eric Courtright  
Compliance Data Section - Karen Nowak  
Administrative and Development - Janet Mobley  
Technical Support and Modeling - Michele Boner

# **PART 70 MINOR SOURCE MODIFICATION OFFICE OF AIR MANAGEMENT**

**Eli Lilly and Company, Tippecanoe Laboratories  
1650 Lilly Road  
Shadeland, Indiana 47902**

(herein known as the Permittee) is hereby authorized to construct and operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this approval.

This approval is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Source Modification No.: 157-12124-00006	
Issued by: Paul Dubenetzky, Branch Chief Office of Air Management	Issuance Date:

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## SECTION A

## SOURCE SUMMARY

This approval is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM). The information describing the emission units contained in conditions A.1 through A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this approval pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

### A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

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The Permittee owns and operates a stationary pharmaceutical manufacturing plant.

Responsible Official: Kenny McCleary  
Source Address: 1650 Lilly Road, Shadeland, Indiana 47905  
Mailing Address: P.O. Box 685, Lafayette, Indiana 47902  
Phone Number: 765-477-4006  
SIC Code: 2834 & 2879  
County Location: Tippecanoe  
County Status: Attainment for all criteria pollutants  
Source Status: Part 70 Permit Program  
Major Source, under PSD or Emission Offset Rules;  
Major Source, Section 112 of the Clean Air Act

### A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

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This stationary source is approved to construct and operate the following emission units and pollution control devices:

- (a) One (1) 500 gallon general process tank, designated as T31A still tank 693, with a maximum capacity of sixty (60) gallons of solvent per minute, and controlled by the existing RTOs or condenser for VOC emissions, and an existing scrubber for SO<sub>2</sub> emissions, and exhausting to two(2) stacks, identified as RTO1 and/or RTO2. CO and NOx emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.

### A.3 Part 70 Permit Applicability [326 IAC 2-7-2]

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This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

- (a) It is a major source, as defined in 326 IAC 2-7-1(22);
- (b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

## **SECTION B                      GENERAL CONSTRUCTION CONDITIONS**

### **B.1      Permit No Defense [IC 13]**

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This approval to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

### **B.2      Definitions [326 IAC 2-7-1]**

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Terms in this approval shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, any applicable definitions found in IC 13-11, 326 IAC 1-2 and 326 IAC 2-7 shall prevail.

### **B.3      Effective Date of the Permit [IC13-15-5-3]**

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Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

### **B.4      Revocation of Permits [326 IAC 2-1.1-9(5)][326 IAC 2-7-10.5(i)]**

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Pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the Commissioner may revoke this approval if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

## SECTION C GENERAL OPERATION CONDITIONS

### C.1 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]

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- (a) Where specifically designated by this approval or required by an applicable requirement, any application form, report, or compliance certification submitted under this approval shall contain certification by a responsible official of truth, accuracy, and completeness. This certification, shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- (b) One (1) certification shall be included, on the attached Certification Form, with each submittal.
- (c) A responsible official is defined at 326 IAC 2-7-1(34).

### C.2 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]

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- (a) If required by specific condition(s) in Section D of this approval, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMP) within ninety (90) days after issuance of this approval, including the following information on each facility:
  - (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
  - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions;
  - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If due to circumstances beyond its control, the PMP cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management  
Compliance Branch, Office of Air Management  
100 North Senate Avenue, P. O. Box 6015  
Indianapolis, Indiana 46206-6015

- (b) The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that failure to implement the Preventive Maintenance Plan does not cause or contribute to a violation of any limitation on emissions or potential to emit.
- (c) PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM. IDEM, OAM, may require the Permittee to revise its Preventive Maintenance Plan whenever lack of proper maintenance causes or contributes to any violation.

### C.3 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

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- (a) The Permittee must comply with the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval.
- (b) Any application requesting an amendment or modification of this approval shall be submitted to:

Indiana Department of Environmental Management

Permits Branch, Office of Air Management  
100 North Senate Avenue, P.O. Box 6015  
Indianapolis, Indiana 46206-6015

Any such application should be certified by the "responsible official" as defined by 326 IAC 2-7-1(34) only if a certification is required by the terms of the applicable rule

- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

#### C.4 Opacity [326 IAC 5-1]

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Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in this approval:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

#### C.5 Operation of Equipment [326 IAC 2-7-6(6)]

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Except as otherwise provided in this approval, all air pollution control equipment listed in this approval and used to comply with an applicable requirement shall be operated at all times that the emission unit vented to the control equipments are operation.

### Testing Requirements [326 IAC 2-7-6(1)]

#### C.6 Performance Testing [326 IAC 3-6][326 IAC 2-1.1-11]

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- (a) Compliance testing on new emission units shall be conducted within 60 days after achieving maximum production rate, but no later than 180 days after initial start-up, if specified in Section D of this approval. All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this approval, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAM.

A test protocol, except as provided elsewhere in this approval, shall be submitted to:

Indiana Department of Environmental Management  
Compliance Data Section, Office of Air Management  
100 North Senate Avenue, P. O. Box 6015  
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days prior to the intended test date. The Permittee shall submit a notice of the actual test date to the above address so that it is received at least two weeks prior to the test date.

- (b) All test reports must be received by IDEM, OAM within forty-five (45) days after the completion of the testing. An extension may be granted by the IDEM, OAM, if the source submits to IDEM, OAM, a reasonable written explanation within five (5) days prior to the end of the initial forty-five (45) day period.

The documentation submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

#### **Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]**

##### **C.7 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]**

Compliance with applicable requirements shall be documented as required by this approval. All monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management  
Compliance Branch, Office of Air Management  
100 North Senate Avenue, P. O. Box 6015  
Indianapolis, Indiana 46206-6015

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

#### **Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]**

##### **C.8 Compliance Monitoring Plan - Failure to Take Response Steps [326 IAC 2-7-5][326 IAC 2-7-6] [326 IAC 1-6]**

- (a) The Permittee is required to implement a compliance monitoring plan to ensure that reasonable information is available to evaluate its continuous compliance with applicable requirements. This compliance monitoring plan is comprised of:
- (1) This condition;
  - (2) The Compliance Determination Requirements in Section D of this approval;
  - (3) The Compliance Monitoring Requirements in Section D of this approval;
  - (4) The Record Keeping and Reporting Requirements in Section C (Monitoring Data Availability, General Record Keeping Requirements, and General Reporting Requirements) and in Section D of this approval; and
  - (5) A Compliance Response Plan (CRP) for each compliance monitoring condition of this approval. CRP's shall be submitted to IDEM, OAM upon request and shall be subject to review and approval by IDEM, OAM. The CRP shall be prepared within ninety (90) days after issuance of this approval by the Permittee and maintained on site, and is comprised of :



- (A) Response steps that will be implemented in the event that compliance related information indicates that a response step is needed pursuant to the requirements of Section D of this approval; and
  - (B) A time schedule for taking such response steps including a schedule for devising additional response steps for situations that may not have been predicted.
- (b) For each compliance monitoring condition of this approval, appropriate response steps shall be taken when indicated by the provisions of that compliance monitoring condition. Failure to perform the actions detailed in the compliance monitoring conditions or failure to take the response steps within the time prescribed in the Compliance Response Plan, shall constitute a violation of the approval unless taking the response steps set forth in the Compliance Response Plan would be unreasonable.
- (c) After investigating the reason for the excursion, the Permittee is excused from taking further response steps for any of the following reasons:
  - (1) The monitoring equipment malfunctioned, giving a false reading. This shall be an excuse from taking further response steps providing that prompt action was taken to correct the monitoring equipment.
  - (2) The Permittee has determined that the compliance monitoring parameters established in the approval conditions are technically inappropriate, has previously submitted a request for an administrative amendment to the approval, and such request has not been denied or;
  - (3) An automatic measurement was taken when the process was not operating; or
  - (4) The process has already returned to operating within "normal" parameters and no response steps are required.
- (d) Records shall be kept of all instances in which the compliance related information was not met and of all response steps taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

C.9 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]  
[326 IAC 2-7-6]

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- (a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this approval exceed the level specified in any condition of this approval, the Permittee shall take appropriate corrective actions. The Permittee shall submit a description of these corrective actions to IDEM, OAM, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. IDEM, OAM shall notify the Permittee within thirty (30) days, if the corrective actions taken are deficient. The Permittee shall submit a description of additional corrective actions taken to IDEM, OAM within thirty (30) days of receipt of the notice of deficiency. IDEM, OAM reserves the authority to use enforcement activities to resolve noncompliant stack tests.
- (b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAM that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAM

may extend the retesting deadline. Failure of the second test to demonstrate compliance with the appropriate approval conditions may be grounds for immediate revocation of the approval to operate the affected facility.

The documents submitted pursuant to this condition do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

## **Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]**

### **C.10 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)]**

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- (a) With the exception of performance tests conducted in accordance with Section C-Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this approval shall be performed at all times the equipment is operating at normal representative conditions.
- (b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this approval is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this approval.
- (c) If the equipment is operating but abnormal conditions prevail, additional observations and sampling should be taken with a record made of the nature of the abnormality.
- (d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.
- (e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.
- (f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements stated in (a) above.

### **C.11 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]**

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- (a) Records of all required monitoring data and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years and available upon the request of an IDEM, OAM, representative. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.
- (b) Records of required monitoring information shall include, where applicable:
  - (1) The date, place, and time of sampling or measurements;
  - (2) The dates analyses were performed;
  - (3) The company or entity performing the analyses;

- (4) The analytic techniques or methods used;
  - (5) The results of such analyses; and
  - (6) The operating conditions existing at the time of sampling or measurement.
- (c) Support information shall include, where applicable:
  - (1) Copies of all reports required by this approval;
  - (2) All original strip chart recordings for continuous monitoring instrumentation;
  - (3) All calibration and maintenance records;
  - (4) Records of preventive maintenance shall be sufficient to demonstrate that failure to implement the Preventive Maintenance Plan did not cause or contribute to a violation of any limitation on emissions or potential to emit. To be relied upon subsequent to any such violation, these records may include, but are not limited to: work orders, parts inventories, and operator's standard operating procedures. Records of response steps taken shall indicate whether the response steps were performed in accordance with the Compliance Response Plan required by Section C - Compliance Monitoring Plan - Failure to take Response Steps, of this approval, and whether a deviation from an approval condition was reported. All records shall briefly describe what maintenance and response steps were taken and indicate who performed the tasks.
- (d) All record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance.

## SECTION D.1 FACILITY OPERATION CONDITIONS

### Facility Description [326 IAC 2-7-5(15)]

- (a) One (1) 500 gallon general process tank, designated as T31A still tank 693, with a maximum capacity of sixty (60) gallons of solvent per minute, and controlled by the existing RTOs or condenser for VOC emissions, and an existing scrubber for SO<sub>2</sub> emissions, and exhausting to two(2) stacks, identified as RTO1 and/or RTO2. CO and NOx emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.

### Emissions Limitation and Standards

#### D.1.1 Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing (326 IAC 8-5-3)

- (a) Pursuant to 326 IAC 8-5-3 the following outlet gas temperature when using condensers to control the VOC emissions from these process tanks(still tank 693) including the existing facilities at the plant shall not exceed the following:
- (1) minus twenty-five degrees Celsius (-25 °C) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (five and eight-tenths (5.8) pounds per square inch);
  - (2) minus fifteen degrees Celsius (-15 °C) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (two and nine-tenths (2.9) pounds per square inch);
  - (3) zero degrees Celsius (0 °C) when condensing VOC of vapor pressure greater than ten (10) kilo Pascals (one and five-tenths (1.5) pounds per square inch);
  - (4) ten degrees Celsius (10 °C) when condensing VOC of vapor pressure greater than seven (7) kilo Pascals (one (1) pounds per square inch); or
  - (5) twenty -five degrees Celsius (25 °C) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascals (five-tenths (0.5) pounds per square inch).
- (b) Pursuant to 326 IAC 8-5-3(b)(1)(C), when using equivalent controls, the VOC emissions shall be reduced by at least as much as they would be by using a surface condenser which meets the requirements of conditions (a)(1) through (a)(5).

### Compliance Determination Requirements

#### D.1.2 Testing Requirements [326 IAC 2-7-6(1),(6)][326 IAC 2-1.1-11]

The Permittee is not required to test the facility by this permit. The testing required for this facility will be deferred and shall follow the schedule in the Title V Permit, to determine compliance with 326 IAC 8-5-3. However, IDEM may require compliance testing when necessary to determine if the facilities are in compliance. If testing is required by IDEM compliance with Condition D.1.1 shall be determined by a performance test conducted in accordance with Section C - Performance Testing.

#### D.1.3 Volatile Organic Compounds 326 IAC 8-5-3(b)(5)(6)

- (a) Pursuant to 326 IAC 8-5-3(b)(5) the Permittee shall install covers on all in process tanks that contain VOC's. These covers shall be kept closed unless production sampling, maintenance, or inspection procedures require operator access.
- (b) Pursuant to 326 IAC 8-5-3(b)(6) the Permittee shall repair all visible leaks containing VOC. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

#### D.1.4 Monitoring For VOC Emissions

- (a) The VOC emissions from the proposed general replacement process tank(still tank 693) shall be in compliance with 326 IAC 8-5-3 provided that:
  - (1) the Regenerative Thermal Oxidizers (RTO) or Condensers (when Lilly elects to control the VOC by condensers) shall operate at all times the equipment being controlled is in operation;
  - (2) when the VOC emissions from the proposed general process tank including the existing facilities are controlled by the RTO, the RTO's operating temperature shall be maintained at 1600°F, or the temperature determined during the most recent stack tests, to maintain at least 90% destruction of the volatile organic compounds. The operating temperature of the RTO shall be recorded and monitored continuously;
  - (3) when the VOC emissions from the proposed general process tank including the existing facilities are controlled by the condensers, the outlet gas temperature shall be equal to or less than that specified by 326 IAC 8-5-3, see condition D.1.1;
  - (4) the Permittee records the time during which the RTO or condensers, serving the proposed process tank, including the existing facilities, were not operated;
  - (5) the Permittee records the reason the RTO or condensers were not operated;
  - (6) the Permittee records the corrective actions taken to bring the RTO or condensers to normal operation; and
  - (7) the Permittee records the number of hours the proposed general process tank, including the existing facilities were vented to points other than the RTO or a condenser complying with 326 IAC 8-5-3.

#### D.1.5 National Emission Standards for Hazardous Air Pollutants (NESHAPs) 40 CFR Part 63, Subparts I and H

That the owner or operator shall implement the Lilly Leak Detection and Repair (LDAR) Program, most recently approved by the Office of Air Management, to reduce fugitive emissions from processes that use methylene chloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.

#### D.1.6 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production)

The proposed general replacement process tank(still tank 693) is subject to 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) and shall be in compliance with this NESHAP by the compliance date.

#### D.1.7 Malfunction Condition

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Pursuant to 326 IAC 1-6-2 (Records; Notice of Malfunction):

- (a) A record of all malfunctions, including startups or shutdowns of any facility or emission control equipment, which result in violations of applicable air pollution control regulations or applicable emission limitations shall be kept and retained for a period of three (3) years and shall be made available to the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM) or appointed representative upon request.
- (b) When a malfunction of any facility or emission control equipment occurs which lasts more than one (1) hour, said condition shall be reported to OAM. The Permittee is encouraged, but not required, to use the Malfunction Report Form (2 pages) attached to this permit. Notification shall be made by telephone or facsimile, as soon as practicable, but in no event later than four (4) daytime business hours after the beginning of said occurrence.
- (c) Failure to report a malfunction of any emission control equipment subject to the requirements of 326 IAC 1-6 shall constitute a violation of 326 IAC 1-6 and any other applicable rules. Information of the scope and expected duration of the malfunction shall be provided, including the items specified in 326 IAC 1-6-2(a)(1) through (6).
- (d) Malfunction is defined as any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner.

### Record Keeping and Reporting Requirements

#### D.1.8 Record Keeping Requirements

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- (a) The Permittee shall maintain records in accordance with (1) through (3) as follows:
  - (1) The malfunction report of the RTOs; and other malfunction reports of the facilities when the RTO is operating but the facility is not venting to the RTO;
  - (2) The RTO's operating temperature;
  - (3) The number of hours the proposed general process tank including existing facilities were vented to points other than the RTO or the condenser; and
- (b) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
OFFICE OF AIR MANAGEMENT  
COMPLIANCE DATA SECTION**

**PART 70 SOURCE MODIFICATION  
CERTIFICATION**

Source Name: Eli Lilly and Company, Tippecanoe Laboratories  
Source Address: 1650 Lilly Road, Shadeland, Indiana 47905  
Mailing Address: P.O. Box 685, Lafayette, Indiana 47902  
Source Modification No.: 157-12124-00006

**This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this approval.**

Please check what document is being certified:

- 9 Test Result (specify) \_\_\_\_\_
- 9 Report (specify) \_\_\_\_\_
- 9 Notification (specify) \_\_\_\_\_
- 9 Other (specify) \_\_\_\_\_

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Date:

## INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT OFFICE OF AIR MANAGEMENT COMPLIANCE DATA SECTION

FAX NUMBER - 317 233-5967

**This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6  
and to qualify for the exemption under 326 IAC 1-6-4.**

THIS FACILITY MEETS THE APPLICABILITY REQUIREMENTS BECAUSE: IT HAS POTENTIAL TO EMIT 25 LBS/HR PARTICULATES ? \_\_\_\_\_, 100 LBS/HR VOC ? \_\_\_\_\_, 100 LBS/HR SULFUR DIOXIDE ? \_\_\_\_\_ OR 2000 LBS/HR OF ANY OTHER POLLUTANT ? \_\_\_\_\_ EMISSIONS FROM MALFUNCTIONING CONTROL EQUIPMENT OR PROCESS EQUIPMENT CAUSED EMISSIONS IN EXCESS OF APPLICABLE LIMITATION \_\_\_\_\_.

THIS MALFUNCTION RESULTED IN A VIOLATION OF: 326 IAC \_\_\_\_\_ OR, PERMIT CONDITION # \_\_\_\_\_ AND/OR PERMIT LIMIT OF \_\_\_\_\_

THIS INCIDENT MEETS THE DEFINITION OF 'MALFUNCTION' AS LISTED ON REVERSE SIDE ?    Y        N

THIS MALFUNCTION IS OR WILL BE LONGER THAN THE ONE (1) HOUR REPORTING REQUIREMENT ?    Y        N

COMPANY: Eli Lilly and Company PHONE NO. (765) 477-4867

LOCATION: (CITY AND COUNTY) Shadeland, Indiana

PERMIT NO. 157-10818 AFS PLANT ID: 157-00006 AFS POINT ID: \_\_\_\_\_ INSP: \_\_\_\_\_

CONTROL/PROCESS DEVICE WHICH MALFUNCTIONED AND REASON:

\_\_\_\_\_

\_\_\_\_\_

—

DATE/TIME MALFUNCTION STARTED: \_\_\_\_/\_\_\_\_/ 19\_\_\_\_    \_\_\_\_\_ AM /  
PM

ESTIMATED HOURS OF OPERATION WITH MALFUNCTION CONDITION:

DATE/TIME CONTROL EQUIPMENT BACK-IN SERVICE \_\_\_\_/\_\_\_\_/ 19\_\_\_\_    \_\_\_\_\_ AM/PM

TYPE OF POLLUTANTS EMITTED: TSP, PM-10, SO<sub>2</sub>, VOC, OTHER: \_\_\_\_\_

ESTIMATED AMOUNT OF POLLUTANT EMITTED DURING MALFUNCTION:

\_\_\_\_\_

\_\_\_\_\_

MEASURES TAKEN TO MINIMIZE EMISSIONS:

\_\_\_\_\_

\_\_\_\_\_

REASONS WHY FACILITY CANNOT BE SHUTDOWN DURING REPAIRS:

CONTINUED OPERATION REQUIRED TO PROVIDE ESSENTIAL\* SERVICES:

CONTINUED OPERATION NECESSARY TO PREVENT INJURY TO  
PERSONS: \_\_\_\_\_

CONTINUED OPERATION NECESSARY TO PREVENT SEVERE DAMAGE TO  
EQUIPMENT: \_\_\_\_\_

INTERIM CONTROL MEASURES: (IF APPLICABLE)

\_\_\_\_\_

\_\_\_\_\_



Eli Lilly and Company, Tippecanoe Laboratories  
Shadeland, Indiana  
Permit Reviewer: Spahi

Page 16 of 17  
Source Modification No. 157-12124-00006

MALFUNCTION REPORTED BY: \_\_\_\_\_ TITLE: \_\_\_\_\_

(SIGNATURE IF FAXED)

MALFUNCTION RECORDED BY: \_\_\_\_\_ DATE: \_\_\_\_\_ TIME: \_\_\_\_\_

FAX NUMBER - 317 233-5967

\*SEE REVERSE

PAGE 1 OF 2

**Please note - This form should only be used to report malfunctions  
applicable to Rule 326 IAC 1-6 and to qualify for  
the exemption under 326 IAC 1-6-4.**

**326 IAC 1-6-1      Applicability of rule**

Sec. 1. The requirements of this rule (326 IAC 1-6) shall apply to the owner or operator of any facility which has the potential to emit twenty-five (25) pounds per hour of particulates, one hundred (100) pounds per hour of volatile organic compounds or SO<sub>2</sub>, or two thousand (2,000) pounds per hour of any other pollutant; or to the owner or operator of any facility with emission control equipment which suffers a malfunction that causes emissions in excess of the applicable limitation.

**326 IAC 1-2-39 “Malfunction” definition**

Sec. 39. Any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner. (Air Pollution Control Board; 326 IAC 1-2-39; filed Mar 10, 1988, 1:20 p.m. : 11 IR 2373)

**\*Essential services** are interpreted to mean those operations, such as, the providing of electricity by power plants. Continued operation solely for the economic benefit of the owner or operator shall not be sufficient reason why a facility cannot be shutdown during a control equipment shutdown.

If this item is checked on the front, please explain rationale:

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## Indiana Department of Environmental Management Office of Air Management

### Addendum to the Technical Support Document for a Minor Source Modification to a Part 70 Permit

Source Name: Eli Lilly and Company, Tippecanoe Laboratories  
 Source Location: 1650 Lilly Road, Shadeland, Indiana 47902  
 County: Tippecanoe  
 Construction Permit No.: 157-12124-00006  
 SIC Code: 2834 and 2879  
 Permit Reviewer: Shanti Pahi/drp

The Company has made the following comments related to the permit:

#### Comment 1) Section A.1

The responsible official should be revised to state the name Kenny McCleary. The phone number should be revised to 765-477-4006.

#### Response 1

These changes have been made to the permit.

#### A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

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The Permittee owns and operates a stationary pharmaceutical manufacturing plant.

Responsible Official: ~~Samuel Rodriguez~~ **Kenny McCleary**  
 Source Address: 1650 Lilly Road, Shadeland, Indiana 47905  
 Mailing Address: P.O. Box 685, Lafayette, Indiana 47902  
 Phone Number: 765-477-~~4867~~ **4006**  
 SIC Code: 2834 & 2879  
 County Location: Tippecanoe  
 County Status: Attainment for all criteria pollutants  
 Source Status: Part 70 Permit Program  
 Major Source, under PSD or Emission Offset Rules;  
 Major Source, Section 112 of the Clean Air Act

#### Comment 2) Section B.4

This has never appeared in any previous MSMA's issued, but this is acceptable.

#### Response 2

No changes were made.

#### Comment 3) Section B.5

This has never appeared in any previous MSMA's issued but this is acceptable. Isn't this duplicative of B.4?

#### Response 3

Condition B.5 will be deleted.

~~B.5 Phase Construction Time Frame~~

~~That pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the IDEM may revoke this approval to construct if the:~~

- ~~(a) Construction of process tank has not begun within eighteen (18) months from the effective date of this approval or if during the construction of process tank, work is suspended for a continuous period of one (1) year or more.~~

~~The OAM may extend such time upon satisfactory showing that an extension, formally requested by the Permittee is justified.~~

Comment 4) Section B.6

BACT determination are not required for this MSMA. This is a like-kind tank replacement to which PSD is not applicable. This condition should be deleted. Also, this is not a phased construction. It is the replacement of one tank only.

Response 4

Condition B.6 will be deleted.

~~B.6 BACT Determination for Phase Constructions~~

~~That pursuant to 40 CFR 52.21(j)(4), for phase construction projects, the determination of BACT shall be reviewed and modified as appropriate at the latest reasonable time which occurs no later than eighteen (18) months prior to commencement of construction of each independent phase of the project.~~

Comment 5) Section C.2

The second sentence of C.2(c) should be deleted. This provision, which may require the Permittee to revise its Preventive Maintenance Plan whenever lack of proper maintenance causes or contributes to any violation, is in excess of IDEM's authority and overly vague. The condition deprives Lilly of due process because Lilly is unable to determine the standards by which it will be regulated. Lilly is currently appealing this issue in two other Modification Approvals recently issued.

Response 5

The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

Comment 6) Section C.3

Condition C.3 should be revised in the caption and subsection (a) to include a reference to 326 IAC 2-7-10.5. As currently written, Condition C.3 is not an accurate statement of the law. Presently, the Tippecanoe facility is a Part 70 source but has not received a Title V permit. Accordingly, to amend or modify this approval (due to a modification of the emission unit covered by this MSMA), Lilly must comply with 326 IAC 2-7-10.5. Lilly is currently appealing this issue in two other Modification Approvals recently issued. Aaron Schmoll, IDEM legal< has informally agreed to this revision.

#### Response 6

The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

#### Comment 7) Section C.7

The second sentence in Condition C.7 should be revised to state: All monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of when operations begin.

#### Response 7

For new equipment installed, IDEM believes that the monitoring and record keeping requirements should be followed from the startup of operation. This wording of this condition will be changed as follows:

All monitoring and record keeping requirements not already legally required shall be implemented ~~within ninety (90) days of approval issuance~~ **upon startup**.

#### Comment 8) Section C.8

Condition C.8 should be deleted. This condition requires the Permittee to implement a compliance monitoring plan, including a Compliance Response Plan. The language in this condition is duplicative of language contained in Section D, which spells out clearly the compliance monitoring requirements. Restating those requirements in Condition C.8 is duplicative and unnecessary and could result in multiple violation occurring from a single act or omission. Furthermore, these conditions are in excess of IDEM's authority. Lilly has successfully requested that this condition be deleted from previous MSMA's (157-10818-00006, issued on May 25, 1999 and MSMA 157-11183-00006, issued on October 26, 1999 - both reviewed by Aida DeGuzman from the OAM Permit Review Section). Lilly is currently appealing this condition in a SSMA. Also, see e-mail message from Aaron Schmoll, IDEM Legal, regarding this issue.

#### Response 8

The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

#### Comment 9) Section C.9

The last sentence of Condition C.9(b) (grounds for immediate revocation of the approval) should be deleted. This condition is in excess of IDEM's authority. Lilly is currently appealing this issue in two other Modification Approvals recently issued. Aaron Schmoll, IDEM Legal, has informally agreed to this revision.

#### Response 9

The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

#### Comment 10) Section C.11

Condition C.11(c)(4) should be deleted. Lilly has successfully requested that this condition be deleted from previous MSMAa (157-10818-00006, issued on May 25, 1999 and MSMA 157-11183-00006, issued on October 26, 1999 - both reviewed by Aida DeGuzman from the OAM Permit Review Section).

Condition C.11(d) should be revised to state: All record keeping requirements not already legally required shall be implemented within ninety (90) days of when operations begin.

#### Response 10

The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

For new equipment installed, IDEM believes that the monitoring and record keeping requirements should be followed from the startup of operation. This wording of this condition will be changed as follows:

All monitoring and record keeping requirements not already legally required shall be implemented ~~within ninety (90) days of approval issuance~~ **upon startup**.

#### Comment 11) Section D.1.1

Condition D.1.1(2) should be revised to state: Pursuant to 326 IAC 8-5-3(b)(1)(C), when using equivalent controls, the VOC emissions shall be reduced by at least as much as they would be by using a surface condenser which meets the requirements of conditions (a)(1) through (a)(5).

#### Response 11

This condition has been changed.

(b) ~~Pursuant to 326 IAC 8-5-3(1)(C), when using equivalent controls, the VOC emissions shall be reduced using the Regenerative Thermal Oxidizer (RTO) with a minimum destruction efficiency of 90%.~~ **(b)(1)(C), when using equivalent controls, the VOC emissions shall be reduced by at least as much as they would be by using a surface condenser which meets the requirements of conditions (a)(1) through (a)(5).**

#### Comment 12) Section D.1.5

Condition D.1.5 should be revised to state: That the owner or operator shall implement the Lilly Leak Detection and Repair (LDAR) Program, most recently approved by the Office of Air Management, to reduce fugitive emissions from processes that use methylene chloride. Methylene chloride is not regulated as a VOC and therefore this condition should only reference reduce fugitive emissions and not reduce fugitive VOC emissions.

#### Response 12

This condition will be changed:

D.1.5 National Emission Standards for Hazardous Air Pollutants (NESHAPs) 40 CFR Part 63, Subparts I and H

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That the owner or operator shall implement the Lilly Leak Detection and Repair (LDAR) Program, most recently approved by the Office of Air Management, to reduce fugitive ~~VOC~~ emissions from processes that use methylene chloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.

Comment 13) Section D.1.6

This condition should be revised to state: and shall be in compliance with this NESHAP by the compliance date. This NESHAP has been under litigation and the current proposed compliance date is October 21, 2002 (this is not official yet, so Lilly suggests only a general reference to the compliance date without a date specified).

Response 13

This condition will be changed:

D.1.6 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production)

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The proposed general replacement process tank(still tank 693) is subject to 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) and shall be in compliance with this NESHAP by the ~~year 2004~~ **compliance date**.

## Indiana Department of Environmental Management Office of Air Management

### Technical Support Document (TSD) for a Part 70 Minor Source Modification.

#### Source Background and Description

<b>Source Name:</b>	<b>Eli Lilly and Company, Tippecanoe Laboratories</b>
<b>Source Location:</b>	<b>1650 Lilly Road, Shadeland, Indiana 47902</b>
<b>County:</b>	<b>Tippecanoe</b>
<b>SIC Code:</b>	<b>2834 &amp; 2879</b>
<b>Operation Permit No.:</b>	<b>157-6879-00006</b>
<b>Operation Permit Issuance Date:</b>	<b>Not yet issued</b>
<b>Minor Source Modification No.:</b>	<b>157-12124-00006</b>
<b>Permit Reviewer:</b>	<b>Spahi</b>

The Office of Air Management (OAM) has reviewed a modification application from Eli Lilly and Company, Tippecanoe Laboratories relating to the construction(replacement of tank 693) of the following emission units and pollution control devices:

- (a) One (1) 500 gallon general process tank, designated as T31A still tank 693, with a maximum capacity of sixty (60) gallons of solvent per minute, and controlled by the existing RTOs or condenser for VOC emissions, and an existing scrubber for SO<sub>2</sub> emissions, and exhausting to two(2) stacks, identified as RTO1 and/or RTO2. CO and NO<sub>x</sub> emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.

#### History

On March 31, 2000, Eli Lilly and Company, Tippecanoe Laboratories submitted an application to the OAM requesting to replace one(1) general process tank. Eli Lilly and Company, Tippecanoe Laboratories applied for a Part 70 permit on October 10, 1996, and it is still pending for issuance.

#### Enforcement Issue

There are no enforcement actions pending.

#### Stack Summary

Stack ID	Operation	Height (feet)	Diameter (feet)	Flow Rate (acfm)	Temperature (°F)
RTO1	Still Tank 693	125	9	98,000	170
or RTO2	Still Tank 693	125	9	105,000	125



## Recommendation

The staff recommends to the Commissioner that the Part 70 Minor Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on March 31, 2000.

## Emission Calculations

The calculations submitted by the applicant have been verified and found to be accurate and correct. These calculations are provided in Appendix A of this document (19 pages).

## Potential To Emit of Modification

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA."

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	0.0
PM-10	0.0
SO <sub>2</sub>	15.15
VOC	0.74
CO	9.88
NO <sub>x</sub>	0.85
Total Reduced Sulfur	0.89
H <sub>2</sub> S	0.15
Reduced Sulfur	0.15

HAP's	Potential To Emit (tons/year)
HCL(gas)	6.00
Methyl Mercaptan	0.74
TOTAL	6.74

## Justification for Modification

The Part 70 Operating permit is being modified through a Part 70 Minor Source Modification. This modification is being performed pursuant to 326 IAC 2-7-10.5(d)(4)(B)(i) because the potential to emit(PTE) of SO<sub>x</sub> is greater than or equal to ten(10) tons per year but less than twenty-five(25) tons per year.

### County Attainment Status

The source is located in Tippecanoe County.

Pollutant	Status
PM-10	Attainment
SO <sub>2</sub>	Attainment
NO <sub>2</sub>	Attainment
Ozone	Attainment
CO	Attainment
Lead	Attainment

- (a) Volatile organic compounds (VOC) and oxides of nitrogen (NO<sub>x</sub>) are precursors for the formation of ozone. Therefore, VOC and NO<sub>x</sub> emissions are considered when evaluating the rule applicability relating to the ozone standards. Tippecanoe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NO<sub>x</sub> emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (b) Tippecanoe County has been classified as attainment or unclassifiable for SO<sub>x</sub>. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

### Source Status

Existing Source PSD or Emission Offset Definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Pollutant	Emissions (tons/year)
PM	682.1
PM-10	682.1
SO <sub>2</sub>	5626.0
VOC	5351.0
CO	363.0
NO <sub>x</sub>	2834.0

- (a) This existing source is a major stationary source because an attainment regulated pollutant is emitted at a rate of 100 tons per year or more, and it is one of the 28 listed source categories.
- (b) These emissions are based upon AIRS Facility Quick Look Report, updated January 22, 1999.

### Potential to Emit of Modification After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

	Potential to Emit (tons/year)									
Process/facility	PM	PM-10	SO <sub>2</sub>	VOC	CO	NO <sub>x</sub>	TRS	H <sub>2</sub> S	Red. Sulfur	HAPs
Still Tank 693	0.0	0.0	15.15	0.74	9.88	0.85	0.89	0.15	0.15	0.74*
										6.00**
Net Emissions	0.0	0.0	15.15	0.74	9.88	0.85	0.89	0.15	0.15	6.74
PSD Significant Levels	25	15	40	40	100	40	10	10	10	-

Note: \* = Methyl Mercaptan \*\* = HCL(gas)

This modification to an existing minor stationary source is not major because the emission increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, and 40 CFR 52.21, the PSD requirements do not apply.

#### Federal Rule Applicability

- (a) (i) This tank is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.110b, Subpart Kb - Standards of Performance for Volatile Organic Liquid Storage Vessels), because this tank is not used for VOC storage purposes.
- (ii) This tank is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.480, Subpart VV - Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry (SOCMI)), because this tank has a design capacity less than 1000 Mg/year.
- (iii) The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.610, Subpart III, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes), because this tank is not an air oxidation unit.
- (iv) This tank is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.660, Subpart NNN, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations), because this tank is operated as a batch reactor.
- (v) This tank is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.700, Subpart RRR, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes), because this tank is operated as a batch reactor.
- (b) (i) The tank is subject to National Emission Standards for Hazardous Air Pollutants(NESHAP), 326 IAC 14,(40 CFR 63.190(b)(5), Subpart H and I(40 CFR Part 63, Subpart H - National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks and 40 CFR Part 63, Subpart I -National

Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks)) when Methylene Chloride is used in them for pharmaceutical synthesis operations. Eli Lilly will comply with these requirements, with the implementation of Eli Lilly's LDAR program, when Methylene Chloride is used in the tanks..

- (ii) 40 CFR Part 63, Subpart B - Requirements for Control Technology Determinations for Major Sources in Accordance with the Clean Air Act Amendments of 1990, Sections 112(g)(2)(B).

The requirements of Part 63.40 through Part 63.44 of this Subpart apply to any owner, or operator who construct or reconstruct a major source of HAPs after the effective date of section 112(g)(2)(B) and the effective date of a Title V permit Program in the State or local jurisdiction in which the major source in question has been specifically exempted from regulation under a standard issued pursuant to sections 112(d), 112(h) or 112(j) and incorporated in another subpart of part 63.

- (iii) The proposed general replacement process tank, T31A still tank 693 is regulated under 40 CFR Part 63, Subpart GGG - National Emission Standards for Hazardous Air Pollutants for Pharmaceutical Production, which was promulgated on September 21, 1998. These process tanks shall be in compliance with this NESHAP by the year 2001.

#### **State Rule Applicability - Individual Facilities**

##### **326 IAC 7 (Sulfur Dioxide Emission Limitation)**

This process tank does not have the potential to emit more than twenty-five (25) tons per year or ten(10) pounds per hour of sulfur dioxide. Therefore, 326 IAC 7 does not apply.

##### **326 IAC 8-5-3 (Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing Operations)**

This rule applies to the manufacture of pharmaceutical products by chemical synthesis. This section applies to all facilities emitting volatile organic compounds, including reactors, distillation units, dryers, storage of organic compounds , transfer of organic compounds, extraction equipment , filters, crystallizers, and centrifuges that have the potential to emit 15 pounds per day or more. The sections that are applicable to Lilly are (b)(1), (5) and (6).

Section (b)(1) of this rule requires that the VOC emissions coming from all reactors, distillation operation, crystallizers, centrifuges, and vacuum dryers shall be controlled by condensers or equivalent controls. The approximate control efficiency required by 326 IAC 8-5-3(b)(1) when using acetone, which has the worst volatility is around 90%.

Lilly is in compliance with this section of the rule, controlling the VOC emissions using either condensers in series with the Regenerative Thermal Oxidizer (RTO), or using the RTO alone. Lilly typically uses the existing RTO to control point source VOC emission from the tanks. The RTO, which has been demonstrated to achieve VOC removal efficiency in excess of 97%, will meet and exceed the requirement of the rule. If the RTO cannot be used due to safety issues, an alternative control device may be used. An analysis to demonstrate the alternative controls are equivalent controls will be done before they are used. Lilly would like to continue manufacturing operations in the process vessels included in this application using other existing pollution control equipment that complies with 326 IAC 8-5-3.

Section(b)(5) of this rule requires the owner or operator to install covers on all in process tanks that contain VOC's. Lilly complies with this section by using covers on all in

process tanks, these covers are closed unless production sampling, maintenance, or inspection procedures require operator access.

Section (b)(6) of this rule requires the owner or operator to repair all visible leaks containing VOC. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

## **Conclusion**

The construction of this proposed modification shall be subject to the conditions of the attached proposed Part 70 Minor Source Modification No. 157-12124-00006.